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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,261	10/05/2001	John P. McKearn	6794F-000040/US(3167/8Z)	7559
47376	7590	01/18/2006	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C.			WEBMAN, EDWARD J	
7700 BONHOMME			ART UNIT	
SUITE 400			PAPER NUMBER	
ST LOUIS, MO 63105			1616	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,261	Applicant(s) MCKEARN ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 141, 144-162 and 166-172 is/are pending in the application.
- 4a) Of the above claim(s) 147-162, 166-172 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 141 and 144-146 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of lung cancer in the reply filed on 10/26/05 is acknowledged. The traversal is on the ground(s) that there is no serious burden to search. This is not found persuasive because applicant's assertion is mere opinion.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 141, 144-146, 155 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '227 in view of Cunningham et al.

Seifert et al teaches celecoxib for treating neoplasia in a subject (claims 1, 9, 12, 18). Lung cancer is specified (page 4 line 32). Use in combination with other antineoplastic agents is disclosed (page 24 line 13-page 28 line 26).

Cunningham teaches the elected alanine compound for treating cancer (see claim 3, column 64 line 25) Combination with other anticancer agents is disclosed (column 6 line 47-column 10 line 25).

It would have been obvious to one of ordinary skill to add the compound of Cunningham et al to the composition of Seifert et al achieve the beneficial effect of a second antineoplastic.

Applicants argue that WO '227 teaches 350 cotherapeutic compounds, not including the claimed integrin antagonist and that Cunningham et al teach 44 cotherapeutic compounds, but do not teach celecoxib. Further, WO '227 teaches 100

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cyclooxygenase –2 inhibitors. Applicants argue each reference separately does not teach the combination; motivation to combine is provided. As to the WO '227 100 cyclooxygenase-2 inhibitors, it is argued they are all equivalent. Applicants themselves claim 48 cyclooxygenase–2 inhibitors; there is no showing that celecoxib is critical to the invention.

Claims 141 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific neoplasia disorders, does not reasonably provide enablement for any neoplasia disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants provide evidence of efficacy only for the elected lung cancer and the nonelected disorders of claims 147-154. Applicants argue that Wands et al was considered enabling for 143 antibodies when only nine were tested and activity proved for four. However, Wands et al concerned a class of chemically related compounds. In contrast, applicants claims a plethora of neoplasia disorders which have a multiplicity of etiologies, therefore, the analogy to Wands et al is unfounded.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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